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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,117	10/06/2005	Susan Banbury	03762.015700	2448

74432 7590 07/08/2010

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,117	BANBURY ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The response filed on **6/9/10** has been entered.

2. Applicant's arguments filed 6/9/10 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1and 3-18 are pending in this office action. Claims 1, 4 and 18 are currently amended.

5. The information disclosure statement (IDS) submitted on 6/09/10 is acknowledged and has been reviewed.

6. The objection of claim 4 is withdrawn due to the amendment of the claim.

7. Claims 1, 4-6 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887) in view of Linnoila et al. (US 4,968,692) are withdrawn because the claims have been amended.

8. Claims 1, 3-4, 12-15 and 17-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Karjalainen et al. **(US 5,292,887)** for the reasons made of record in Paper No. 20091209 and as follows.

Applicant argues that "Karjalainen is directed to substituted imidazole derivatives. As disclosed therein, the compounds "may be administered orally, parenterally or intravenously." Karjalainen fails to disclose or suggest use of the imidazole derivatives in a fast-dispersing, solid dosage form, the benefits of pre-gastric absorption of the active ingredient, or the potential to use the compound in a form which disintegrates within 10 seconds of being placed in the oral cavity".

In response Applicant's limitations of "wherein the fast-dispersing solid dosage form is formulated to disintegrate within 10 seconds of being in the oral cavity" is found not persuasive because there is nothing recited in instant claim 1 that distinguishes Karjalainen solid dosage form from being fast dispersing. Karjalainen teaches the same compound with the same substituents that is administered in a solid dosage form orally. Therefore inherently the solid drug of Karjalainen would provide pre-gastric absorption of the active ingredient that is capable of disintegrating in the oral cavity within 10 seconds.

Thus Applicant's argument is found not persuasive.

9. Claims 1, 3 and 12-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. **(US 5,292,887)** for the reasons made of record in Paper No. 20091209 and as follows.

Applicant argues that whether the dosage form of Karjalainen disperses upon contact with bile is not relevant to the present invention. The presently claimed invention discloses a dosage form whereby the active ingredient is absorbed pre-gastrically by virtue of the fast-dispersing solid dosage form. In the present invention, the active ingredient is intended to be absorbed within 10 seconds in the mucus membranes in the mouth or the pharynx and/or oesophageal mucus membranes, i.e., prior to reaching the bile of the duodenum (small intestine). Karjalainen fails to teach or suggest administering the active in the fast-dispersing solid dosage form of the presently claimed invention.

In response Karjalainen et al. is already discussed in para 7 above, as it relates to the product claimed, versus any intended uses.

10. Claims 1, 4-6 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887) in view of Linnoila et al. (US 4,968,692) record in Paper No. 20091209 and as follows.

Applicant argues that Karjalainen fails to render the presently claimed invention obvious and that Linnoila suffers from the same deficiency as Karjalainen - there is simply no teaching or suggestion of a fast-dispersing, solid dosage form for pre-gastric absorption of the active ingredient which disintegrates within 10 seconds of being placed in the oral cavity.

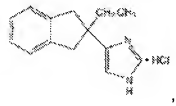
In response see Karjalainen in para 7 above.

Karjalainen et al. is applied here as above in para 5. Additionally Karjalainen teaches that these compounds are employed with pharmaceutically acceptable carriers (see col. 5, lines 25-26).

However Karjalainen fails to teach that the fast-dispersing, solid dosage form comprises a network of active agent's which are water soluble or water-dispersible carriers (as required by instant claims 4-6 and 8).

Linnoila et al is introduced to show compounds of structural similarity to Karjalainen's compound may be in a tablet form and may contain pharmaceutically acceptable carriers such as gelatin and mannitol.

Linnoila et al. teach a similar drug formulation such as (i.e., atipamezole



, wherein Y represents CH2, (i.e., Y in the instant application R3 is ethyl and R 1,2 are hydrogen's see above formula), that are capable of being administered as a tablet (see abstract, col. 1, lines 30-33 and col. 5, lines 27-33, as required by instant claims 1, 12, 17-18). Additionally, Linnoila et al. teach that the tablet may be formulated with additives such as mannitol and gelatin (as required by instant claims 4-6 and 8; see col. 5, lines 43-50).

Since both Karjalainen and Linnoila teach the use of pharmaceutical carriers, one of ordinary skill in the art would have had a reasonable expectation that the base teaching of pharmaceutically acceptable carriers includes gelatin and mannitol as taught by Linnoila et al. It would have been obvious to one of ordinary skill in the art to employ

the specific pharmaceutically acceptable carriers such as mannitol and gelatin as taught by Linnoila, because both Karjalainen and Linnoila teach structurally similar drugs.

11. Claims 1-6 and 8-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887) in view Johnson et al. (US 6,316,027) for the reasons made of record in Paper No. 20091209 and as follows.

Applicant argues that Karjalainen et al and Johnson whether considered separately or in any combination fail to render the claims obvious.

In response Karjalainen is already discussed above.

However Karjalainen is silent to whether their formulation is a fast dispersing solid dosage form which is capable of disintegrating within 10 seconds of being placed in the oral cavity and also fails to teach that the matrix forming agent includes an amino acid (as required by instant claims 2 and 5-11).

Johnson et al. is introduced for its teaching of fast-dispersible solid dosage forms comprising gelatin, mannitol, and an amino-acid.

Johnson et al. teach a pharmaceutical composition for oral administration consisting essentially of a gelatin, a carrier, a solvent, and, an active ingredient (i.e., a dopamine agonist) in a form of a solid, fast-dispersing dosage form capable of promoting pre-gastric absorption of the active ingredient (see abstract, col. 3, lines 35-40) comprising a network of active ingredients and a water-soluble or water dispersible matrix which is inert towards the active ingredient wherein the network having been

obtained by subliming solvent from the composition in the solid state (as required by instant claim 3, see abstract).

Johnson further teaches that the dosage is designed to completely disintegrate within 1 to 30 seconds of being placed in the oral cavity (as required in parts of instant claims 2-3) for the treatment of Parkinson's disease. Johnson also teaches that the matrix may include an amino acid (i.e., glycine), gelatin, mannitol and a cyclic sugar such as cyclodextrin (see col. 6, lines10-30 as required by instant claims 4-11).

Because Karjalainen teaches that their composition can be made into a solid dosage form it would have been obvious to one of ordinary skill in the art to modify the solid dosage form of Karjalainen by incorporating Johnson's fast dispersing solid dosage form because Johnson teaches that these fast dispersing forms are particularly advantageous to patients with swallowing difficulties and are further advantageous because they can be easily disintegrate rapidly in the mouth, thus, minimizing the need of large volumes of water (see col. 3, lines 50-55).

11. Claims 1-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887 in view of Murray et al. (US 6,709,669) for the reasons made of record in Paper No. 20091209 and as follows.

Applicant argues that neither of the prior art would have resulted in the claimed invention.

Karjalainen et al. is applied here as discussed above.

However Karjalainen is silent to whether their formulation is a fast dispersing solid dosage form which is capable of disintegrating within 10 seconds of being placed in the oral cavity and also fails to teach that the matrix forming agent includes an amino acid (as required by instant claims 2 and 5-11).

Murray teaches a pharmaceutical composition comprising a carrier and an active ingredient (e.g., drug, compound, and the like) wherein the carrier is fish gelatin and the composition is in the form of a fast-dispersing dosage form which releases the active ingredient rapidly on contact with a fluid (e.g., saliva, bodily fluids, water, and the like). Preferably, the composition is designed for oral administration and releases the active ingredient rapidly in the oral cavity within 1-10 seconds, wherein the network having been obtained by subliming solvent from a composition in the solid state containing the active ingredient and a solution or dispersion of the carrier in a solvent (see Abstract, and column 3, lines 50-55 and col. 4, lines 1-5, as required by instant claims 1-3). Murray's composition further comprises gelatin, wherein the gelatin is fish gelatin, mannitol, cyclic sugars, amino acid (i.e., glycine) as required by instant claims 4-11 (see col. 5, lines 24-44). Murray further teaches that the active agent may be an anti-diabetic drug (see col. 6, lines 10-11)

However Murray fails to teach use of the recited drug.

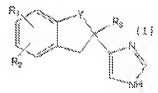
It would have been obvious to one of ordinary skill in the art to expand the composition formulation taught by Karjalainen et al., to include a fish gelatin because Murray teaches that fish gelatin is advantageously used in rapid disintegrating dosage forms because it rapidly releases the active agents (see col. 3, lines 21-24). It would

have been obvious to one of ordinary skill in the art to employ Karjalainen anti-diabetic drug in the fast dispersible solid dosage form of Murray because Murray teaches that anti-diabetic drugs may be used in formulating such fast dispersible solid dosage drugs.

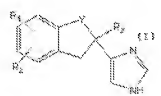
12. Claims 1-18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 25-33 of U.S. Patent Application No. 10/534,091 the reasons made of record in Paper No. 20091209 and as follows.

Applicant argues that claim 1 is directed to a fast dispersing solid dosage form that disintegrates within 10 seconds of being placed in the oral cavity and that copending application claims fails to recite these limitations.

In response the claims of the instant application '117 is directed to a fast



dispersing solid dosage form containing an active ingredient that is capable of disintegrating within 10 seconds of being placed in the mouth and the claims of the copending application '091 are to administering a formulation comprising



oromucosally (i.e., via the mouth through the mucosa membrane, i.e., fast dispersing).

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1-19 and copending application claims 23 and 25-33.

As to the copending application claims 23 and 25-33, these claims refer to administering the claimed active drug via oromucosally which is placing the solid form of the drug in the mouth to disintegrate (see copending claim 23).

One of ordinary skill in the art would have been motivated to use the copending application claims in producing the instant recited claims because both sets of claims are to a formulation that is capable of being dissolved/disintegrated when placed in the oral cavity via the mucosal membrane. Therefore the claimed formulation of instant claims 1-18 would have been used in producing the formulation in the copending claims or vice-versa and therefore are part of the obvious variation of the copending application claims compared to the current application claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations of each other.

13. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
6/25/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649